Remarks

Rejection of Claims 2 and 3 Under 35 U.S.C. § 112 ¶ 2

Claims 2 and 3 stand rejected as indefinite under 35 U.S.C. § 112 ¶ 2. The Office Action rejects claim 2 because there is no antecedent basis for the recitation "said test compound." Claim 2 is amended to recite "a test compound" rather than "said test compound." The Office Action rejects claim 3 as omitting an essential step which recites determining the activity of the FPRL-1 polypeptide in the presence of both the test compound and the regulator. Step (iii) of claim 3 is amended to recite "identifying the test compound as a potential therapeutic agent useful in the treatment of the disease if the activity of the FPRL1 polypeptide is inhibited in the presence of each of the test compound and the compound known to be a regulator."

Please withdraw the rejection.

Rejection of Claims 1-11 Under 35 U.S.C. § 112 ¶ 1

The Office Action maintains the rejection of claims 1-11 as not enabled under 35 U.S.C. § 112 ¶ 1. Applicants respectfully traverse the rejection.

Applicants' previous responses argued that (a) FPRL1 is highly expressed in cardiovascular tissues, thereby indicating an association between FPRL1 and cardiovascular disease; and (b) post-filing date art supports the specification's disclosure that the FPRL1 ligand lipoxin A4 is involved in cardiovascular diseases, respiratory diseases, and genito-urological disorders.

With respect to point (a), the Office Action asserts that, in relation to expression in several non-cardiovascular tissues, "one could conclude that the level of expression of mRNA in cardiovascular tissue is low, and would not predict an association between FPRL1 polypeptide and cardiovascular disease." Office Action at page 4, second full paragraph. Applicants disagree with

this assertion. the skilled reader knows that an organ such as the heart comprises various subcompartments (*e.g.*, atrium or ventricle) in which expression of a gene could be different. The mRNA extracts of heart used to obtain the expression data disclosed in the specification therefore represent the mean expression from all subcompartments. Thus, a higher expression in the left ventricle compared to the heart as a whole does not permit one to conclude that there is no association between FPRL1 and cardiovascular disease. In fact, the skilled artisan knows that the left ventricle is substantially involved in the disease pathology of cardiovascular disorders. Thus, the high expression in a subcompartment such as the left ventricle strengthens the association between FPRL1 and cardiovascular disease.

With respect to point (b), the Office Action merely argues that "the post-filing date evidence does not compensate for the lack [of] guidance in the specification as to whether one is screening for an agent that agonizes or antagonizes the FPRL1 receptor." Office Action at page 4, last full paragraph. No undue experimentation is required to screen for activators or inhibitors, as the screening methods permit identification of both.

The Patent Office has not met its burden of establishing a *prima facie* case of non-enablement. Please withdraw the rejection.

Rejection of Claims 1, 2, 4, 5, and 10 Under 35 U.S.C. § 102(b)

The Office Action maintains the rejection of claims 1, 2, 4, 5, and 10 under 35 U.S.C. § 102(b) as anticipated by Gronert.[1] Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Applicants have explained that independent claims 1 and 2 each recite a step which refers to particular disorders which Gronert does not disclose; therefore Gronert does not anticipate claims 1, 2, 4, 5, or 10. The Office Action responds to this argument by contending that Applicants have not provided an enabling disclosure. Paragraph bridging pages 5 and 6 of the Office Action. Applicants disagree with this assertion (see above); in any event, whether Applicants' disclosure is irrelevant for determining anticipation. Gronert does not disclose any of the recited disorders, including the elected species of cardiovascular diseases. Gronert therefore does not anticipate independent claims 1 or 2 or dependent claims 4, 5, or 10.

Please withdraw the rejection.

[1] Gronert *et al.*, *J. Exp. Med. 187*, 1285-94, April 20, 1998.

Rejection of Claims 1-6 and 8-10 Under 35 U.S.C. § 103(a)

The Office Action maintains the three rejections under 35 U.S.C. § 103(a), each based on Gronert as the primary reference:

- claims 1-6 and 8-10 over Gronert in view of Fiore;[2]
- claim 7 over Gronert in view of Ramakrishnan;[3] and
- claims 1 and 11 over Gronert in view of Seo.[4]

Applicants' previous response explained that there is no *prima facie* case of obviousness at least because, as explained above, Gronert does not disclose a connection between the recited polypeptide and any of the diseases recited in the bodies of independent claims 1 and 2. None of the secondary references remedies this deficiency. Thus, a *prima facie* case of obviousness has not been made over Gronert in view of any of the cited references. The Office Action responds to this argument by contending that Applicants have not provided an enabling disclosure. Office Action at page 7 ¶ 2. Again, Applicants disagree with this assertion (see above). Moreover, whether Applicants' disclosure is irrelevant for determining obviousness.

Please withdraw the rejection.

Respectfully submitted,
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[2] Fiore *et al.*, *J. Exp. Med. 180*, 253-60, 1994.

[3] Ramakrishnan, US 2002/0058259, filed March 14, 2001.

[4] Seo *et al.*, *J. Immunol. 158*, 1895-1901, 1997.